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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,508	06/05/2006	Young Tae Kim	428.1056	8016
20311 7590 03/03/2009 LUCAS & MERCANTI, LLP 475 PARK AVENUE SOUTH 15TH FLOOR NEW YORK, NY 10016			EXAMINER SAIDHA, TEKCHAND	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 03/03/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,508	Applicant(s) KIM ET AL.	
	Examiner Tekchand Saidha	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-19 are present in this application.

2. ***Election***

Applicant's election of Group IV (claims 18 & 19) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 18 & 19 are under consideration in this Office Action.

4. **Claims withdrawn:**

Claims 1-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. ***Priority***

Acknowledgment is made of applicants' claim for priority based on an applications filed in Republic of Korea on 3/31/2004.

6. ***Drawings***

The drawings are objected to because they lack clarity. Figures 6, 9-14 are blurry and barely legible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the

examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

7. ***Sequence Rules***

The instant specification, Figures 9-14 present amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), but fails to comply with the requirements. According to 37 CFR 1.821-825, every disclosed amino acid sequence of four or more residues or 10 or more nucleotides must be identified by a SEQ ID NO. The amino acid sequences presented do not have SEQ ID NOs. In order to comply with the sequence rules Applicants must identify these sequences by providing SEQ ID NOs, and where required provide a new version of the sequence listing and disk.

8. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

9. ***Claim Rejections - 35 USC § 112*** (first paragraph)

Deposit Requirement

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the [plasmid/microorganism/vector] is required to practice the claimed invention. As such the [plasmid/microorganism/vector] must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the [plasmid/microorganism/vector]. The specification lacks complete deposit information for the deposit of [plasmid/microorganism/vector]. If a deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by

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an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that (a) during pendency of the application, access to the invention will be afforded to the Commissioner upon request, (b) all restrictions upon availability to the public will be irrevocable removed upon granting of the patent, (c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer, (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807) and (e) the deposit will be replaced if it should ever become inviable.

Claim 19 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The instant specification on page 47, lines 7-12, provide information on the deposit of Accession No. KCCM-10460 at Korean Culture Center of Microorganisms, an accepted International Depository Authority, however, lack certification of deposit criteria set forth in 37 CFR 1.801-1.809, as explained above.

10. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claims 18-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the word(s) or Phrase(s) –A *Paracoccus haeundaesis* producing ‘astaxanthine,’ which has a 16S rDNA nucleotide sequence represented by SEQ ID NO: 3.

Astaxanthine is spelled as ‘astaxanthin’. The claim is confusing for the manner it is phrased and may read on a naturally occurring *Paracoccus haeundaesis* which will have 16S rDNA, because the nucleic acid sequence is isolated from the said organism.

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The phrase 'represented by' is a relative phrase and it is not clear what other sequences are represented of SEQ ID NO: 3. Deletion of the phrase is suggested.

Suggested language (Claim 18):

An astaxanthin producing *Paracoccus haeundaesis* transformed with a 16S rDNA nucleotide sequence of SEQ ID NO: 3.

Claim 19 recites the phrase 'represented by', which is a relative phrase and it is not clear what other sequences are represented of SEQ ID NO: 3. Deletion of the phrase is suggested.

Suggested language (Claim 19):

The *Paracoccus haeundaesis* of claim 18, which is designated as Accession No. KCCM-10460.

11. *Paracoccus haeundaesis* is an Applicant's designated species and is a strain of *Paracoccus* species gathered from the shores of Haeundae in Busan, Korea (See pages 29-30).

12. **35 U.S.C. § 101**

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 18-19 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter.

In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). *Paracoccus haeundaesis* is an Applicant's designated species and is a strain of *Paracoccus* species gathered from the shores of Haeundae in Busan, Korea (See pages 29-30). This is a product of nature and naturally contains 16SDNA nucleotide sequence represented by SEQ ID NO: 3. Assigning the naturally existing strain an Accession No. does not change the state of its natural existence.

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Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Berry et al. (USP 6989257). Berry et al. teach the transformation of *Paracoccus* species with a 16S rDNA and the production of astaxanthin. See paragraphs 75, 78, 80, 81, 106 & 280, for example. FIG. 2 shows the nucleotide sequence of the gene coding for 16S rDNA in *Paracoccus* sp. strain R-1512 (ATCC 21588) (SEQ ID NO: 12). Below is presented the sequence alignment between Applicants' SEQ ID NO: 3 and prior art sequence of SEQ ID NO: 12, having about 90% sequence similarity. *Paracoccus* species is considered as representative of the organism – while Berry's sequence is considered as representative of SEQ ID NO: 3. The reference anticipates the claims.

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RESULT 7
US-10-166-225A-12
; Sequence 12, Application US/10166225A
; Patent No. 6989257
; GENERAL INFORMATION:
; APPLICANT: BERRY, Alan
; APPLICANT: BRETZEL, Werner
; APPLICANT: HUMBELIN, Markus
; APPLICANT: LOPEZ-ULIBARRI, Rual
; APPLICANT: MAYER, Anne F.
; APPLICANT: YELISEEV, Alexei A.
; TITLE OF INVENTION: IMPROVED ISOPRENOID PRODUCTION
; FILE REFERENCE: C38435/121966
; CURRENT APPLICATION NUMBER: US/10/166,225A
; CURRENT FILING DATE: 2002-06-05
; NUMBER OF SEQ ID NOS: 197
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 12
; LENGTH: 1404
; TYPE: DNA
; ORGANISM: Paracoccus sp. R-1512
US-10-166-225A-12
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Query Match          89.2%;  Score 1297.2;  DB 4;  Length 1404;
Best Local Similarity 95.7%;  Pred. No. 0;
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Matches 1344; Conservative 0; Mismatches 58; Indels 2; Gaps 1;

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Qy      39 GCGGCAGGCTTAACACATGCAAGTCGAGCGAGACCTTCGGGTCTAGCGGCGGACGGGTGA 98
      |||
Db      1 GCGGCAGGCTTAACACATGCAAGTCGAGCGAGGTCTTCGGACCTAGCGGCGGACGGGTGA 60

Qy     99 GTAACGCGTGGGAACGTGCCCTTCTCTACGGAATAGCCCCGGGAACTGGGAGTAATACC 158
      |||
Db     61 GTAACGCGTGGGAACGTGCCCTTCTCTACGGAATAGTCCCGGGAACTGGGTTTAATACC 120

Qy    159 GTATACGCCCTTTGGGGGAAAGATTTATCGGAGAAGGATCGGCCCGCGTTGGATTAGGTA 218
      |||
Db    121 GTATGTGCCCTACGGGGGAAAGATTTATCGGCAAGGATCGGCCCGCGTTGGATTAGGTA 180

Qy    219 GTTGGTGGGGTAATGGCCACCAAGCCGACGATCCATAGCTGGTTTGAGAGGATGATCAG 278
      |||
Db    181 GTTGGTGGGGTAATGGCCTACCAAGCCGACGATCCATAGCTGGTTTGAGAGGATGATCAG 240

Qy    279 CCACACTGGGACTGAGACACGGCCCAGACTCCTACGGGAGGCAGCAGTGGGGAATCTTAG 338
      |||
Db    241 CCACACTGGGACTGAGACACGGCCCAGACTCCTACGGGAGGCAGCAGTGGGGAATCTTAG 300

Qy    339 ACAATGGGGGCAACCTTGATCTAGCCATGCCCGTGAGTGATGAAGGCCCTAGGGTTGTA 398
      |||
Db    301 ACAATGGGGGCAACCTTGATCTAGCCATGCCCGTGAGTGATGAAGGCCCTAGGGTTGTA 360

Qy    399 AAGCTCTTTTCAGCTGGGAAGATAATGACGGTACCAGCAGAAGAAGCCCCGGCTAACTCCG 458
      |||
Db    361 AAGCTCTTTTCAGCTGGGAAGATAATGACGGTACCAGCAGAAGAAGCCCCGGCTAACTCCG 420

Qy    459 TGCCAGCAGCCGCGGTAATACGGAGGGGGCTAGCGTTGTTTCGGAATTACTGGGCGTAAAG 518
      |||
Db    421 TGCCAGCAGCCGCGGTAATACGGAGGGGGCTAGCGTTGTTTCGGAATTACTGGGCGTAAAG 480

Qy    519 CGCACGTGGGCGGACTGGAAAGTCAGAGGTGAAATCCCAGGGGCTCAACCTTGGAAGTACC 578
      |||
Db    481 CGCACGTAGGCGGACTGGAAAGTTGGGGGTGAAATCCCAGGGGCTCAACCTTGGAAGTACC 540

Qy    579 TTTGAAACTATCAGTCTGGAGTTCGAGAGAGGTGAGTGGAAATCCGAGTGTAGAGGTGAA 638
      |||
Db    541 TCCAAAACATCAGTCTGGAGTTCGAGAGAGGTGAGTGGAAATCCGAGTGTAGAGGTGAA 600

Qy    639 ATTCTGTAGATATTCGGAGGAACACCAGTGGCGAAGGCGGCTCACTGGCTCGATACTGACG 698
      |||
Db    601 ATTCTGTAGATATTCGGTGGAAACACCAGTGGCGAAGGCGGCTCACTGGCTCGATACTGACG 660

Qy    699 CTGAGGTGCGAAAGCGTGGGGAGCAAACAGGATTAGATACCCTGGTAGTCCACGCCGTAA 758
      |||
Db    661 CTGAGGTGCGAAAGCGTGGGGAGCAAACAGGATTAGATACCCTGGTAGTCCACGCCGTAA 720

Qy    759 ACGATGAATGCCAGACGTCGGCAAGCATGCTTGTTCGGTGTACACCTAACGGATTAAGCA 818
      |||
Db    721 ACGATGAATGCCAGTCGTCGGGTTGCATGCAATTCGGTGACACACCTAACGGATTAAGCA 780

Qy    819 TTCCGCCTGGGGAGTACGGTCGCAAGATTAAACTCAAAGGAATTGACGGGGGCGGCAC 878
      |||
Db    781 TTCCGCCTGGGGAGTACGGTCGCAAGATTAAACTCAAAGGAATTGACGGGGGCGGCAC 840

Qy    879 AAGCGGTGGAGCATGTGGTTTAATTGCAAGCAACGCGCAGAACCTTACCAACCTTGACA 938
      |||
Db    841 AAGCGGTGGAGCATGTGGTTTAATTGCAAGCAACGCGCAGAACCTTACCAACCTTGACA 900

Qy    939 TGGCAGGACCGCTGGAGAGATTAGCTTTCTCGTAAGAGACCTGCACACAGGTGCTGCAT 998
      |||
Db    901 TCCCTGGACATCCCGAGAGATCGGGCTTTCACCTTCGGTGACCAGGAGACAGGTGCTGCAT 960
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Qy      999  GGCTGTCGTCAGCTCGTGTGAGATGTTCCGGTTAAGTCCGGCAACGAGCGCAACCCAC 1058
        |||||||
Db      961  GGCTGTCGTCAGCTCGTGTGAGATGTTCCGGTTAAGTCCGGCAACGAGCGCAACCCAC 1020

Qy     1059  GTCCCTAGTTGCCAGCATTCAAGTTGGGCACTCTATGGAACTGCCGATGATAAGTCGGAG 1118
        |||||||
Db     1021  GTCCCTAGTTGCCAGCATTCAAGTTGGGCACTCTATGGAACTGCCGATGATAAGTCGGAG 1080

Qy     1119  GAAGGTGTGGATGACGTCAAGTTCTCATGGCCCTTACGGGTGGGGCTACACACGTGCTAC 1178
        |||||||
Db     1081  GAAGGTGTGGATGACGTCAAGTTCTCATGGCCCTTACGGGTGGGGCTACACACGTGCTAC 1140

Qy     1179  AATGGTGGTGACAGTGGGTAAATCCCCAAAAGCCATCTCAGTTCGGATTGTCTCTGCAA 1238
        |||||||
Db     1141  AATGGTGGTGACAGTGGGTAAATCCCCAAAAGCCATCTCAGTTCGGATTGTCTCTGCAA 1200

Qy     1239  CTCGAGGGCATGAAGTTGGAATCGCTAGTAATCGCGGAACAGCATGCCGCGGTGAATACG 1298
        |||||||
Db     1201  CTCGAGGGCATGAAGTTGGAATCGCTAGTAATCGCGGAACAGCATGCCGCGGTGAATACG 1260

Qy     1299  TTCCCGGGCCTTGTACACACCGCCCGTCACACCATGGGAGTTGGTTCTACCCGACGACGC 1358
        |||||||
Db     1261  TTCCCGGGCCTTGTACACACCGCCCGTCACACCATGGGAGTTGGTTCTACCCGACGACGC 1320

Qy     1359  TGCCTAACC--TTCCGGGGGCGAGCGGCCACGGTAGGATCAGCGACTGGGGTGAAGTCG 1416
        |||||
Db     1321  TGCCTAACCCTTCGGGGAGGCGAGCGGCCACGGTAGGATCAGCGACTGGGGTGAAGTCG 1380

Qy     1417  TAACAAGGTAGCCGTAGGGGAACC 1440
        |||||||
Db     1381  TAACAAGGTAGCCGTAGGGGAACC 1404

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14. ***Hyperlink***

The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (for example, page 43, line 15), is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

Applicant's cooperation is requested in correcting all hyperlink(s) which may have been added or were present in the original specification at the time of filing.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached between 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

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Nashaat T. Nashed can be reached on (571) 272 0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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